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Amendment and Response Serial No.: 10/734,682 Confirmation No.: 1223 Filed: 12 December 2003

For: SAMPLE MIXING ON A MICROFLUIDIC DEVICE

### Remarks

The Office Action mailed May 20, 2008 has been received and reviewed. No claims have been amended and new claims 39-41 are presented, leaving claims 1-10 and 30-41 pending after entry of these amendments (claims 11-29 were previously canceled). Reconsideration and withdrawal of the rejections are respectfully requested.

# The 35 U.S.C. § 112, Second Paragraph, Rejection

Claims 1-10 and 30-38 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, it is asserted that "Applicants' [sic] recite 'a normally-closed valve," that "[i]t is unclear as to what the applicants' [sic] are referring to," and that "[c]larification is needed." Office Action, May 20, 2008, page 2.

At the outset, it is noted that neither independent claims 1 and 30 nor dependent claims 3-9 (which depend on claim 1) and 32-38 (which depend on claim 30) recite a "normally-closed valve." As such, it is unclear why claims 1, 3-9, 30, and 32-38 have been included in this 35 U.S.C. § 112, second paragraph, rejection. For the purposes of this response, it is assumed claims 1, 3-9, 30, and 32-38 have been mistakenly included in this rejection and will not be addressed. Nonetheless, this rejection with respect to claims 1, 3-9, 30, and 32-38 is traversed, and, if this rejection is maintained with respect to claims 1, 3-9, 30, and 32-38, Applicants reserve the right to argue the applicability of this to claims 1, 3-9, 30, and 32-38 at a later date.

With respect to claims 2, 10, and 31, this rejection is respectfully traversed.

Dependent claim 2 (which depends on claim 1) recites, *inter alia*, that "the valve of the process chamber is normally-closed." Dependent claim 31 (which depends on claim 30) recites, *inter alia*, that "the valve of the process chamber in at least one sample mixing structure of the two or more sample mixing structures is normally-closed." Independent claim 10 recites, *inter alia*, "a process chamber comprising a delivery port on the proximal side of the process chamber and a normally-closed valve on a distal side of the process chamber."

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The proper standard to apply in assessing a claim under 35 U.S.C. § 112, second paragraph, is whether the claim as a whole "apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph, by providing clear warning to others as to what constitutes infringement of the patent." M.P.E.P. § 2173.02, p. 2100-218 (8th Ed., Rev. 6, September 2007) (citing Solomon v. Kimberly-Clark Corp., 216 F.3d 1372, 1379, 55 U.S.P.Q.2d 1279, 1283 (Fed. Cir. 2000)). Furthermore, the claims are not to be interpreted in a vacuum. Rather, definiteness under 35 U.S.C. § 112, second paragraph, must be determined on whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." M.P.E.P. § 2173.02, p. 2100-219 (8th Ed., Rev. 6, September 2007) (citing Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1576, 1 U.S.PQ.2d 1081, 1088 (Fed. Cir. 1986)).

None of the reasoning presented in support of this rejection addresses why the claims would fail to serve the notice function of 35 U.S.C. §112, second paragraph to one of ordinary skill in the art. Nor does the reasoning discuss why one of ordinary skill in the art would not be able to discern the limits of the claims when the claims are read in light of the specification. As support for Applicants' position that one of ordinary skill in the art would understand the limits of the claims when the claims are read in light of the specification, Applicants note the portion of the specification as filed reproduced below:

The process chamber 40 may preferably include a valve 44 to control movement from the process chamber 40 to the secondary process chamber 50. The valve 44 may preferably be normally closed until opened.

Specification, page 6, lines 15-17.

In view of the above discussion, Applicants respectfully submit that one of ordinary skill in the art would clearly understand the limits of the terms "normally-closed" and "normally-closed" and valve" recited within claims 2, 10, and 31. As such, the claims reciting "normally-closed" and "normally-closed valve" provide clear warning to others as to what constitutes infringement of the patent as required by 35 U.S.C. §112, second paragraph.

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In view of the above, Applicants respectfully submit that a proper rejection under 35 U.S.C. § 112, second paragraph has not been established. Reconsideration and withdrawal of this rejection are, therefore, respectfully requested.

## The 35 U.S.C. § 102 Rejection

Claims 1-3, 6-7, 9-10, 30-32, and 35 were rejected under 35 U.S.C. § 102(b) as being anticipated by Kellogg et al. (U.S. Patent No. 6,302,134). This rejection is respectfully traversed.

For a claim to be anticipated under 35 U.S.C. § 102, each and every element of the claim must be found in a single prior art reference (M.P.E.P. § 2131). Applicants respectfully submit that Kellogg et al. fails to teach each and every element of claims 1-3, 6-7, 9-10, 30-32, and 35.

Each of independent claims 1, 10 and 30 recites that rotation of the sample processing device moves at least a portion of the sample material in the process chamber into the mixing chamber through the mixing port when the mixing port is open. This construction is not disclosed by Kellogg et al. and, as a result, Kellogg et al. cannot anticipate claims 1-3, 6-7, 9-10, 30-32, and 35.

In support of this rejection, the connection between capillary channel (610) and mixing chamber (605) of Kellogg et al. has been equated to the recited "mixing port" and the channels (602) have been equated to the recited process chamber (see, e.g., the following copy of Figure 14 of Kellogg et al. as annotated in the Office Action).

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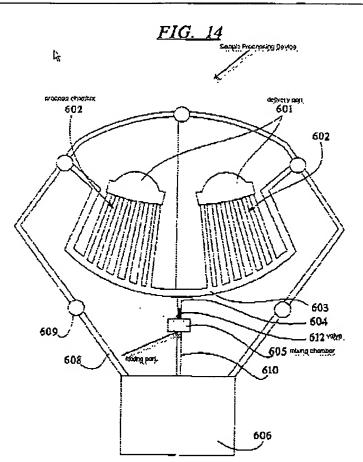


FIG. 14 of Kellogg et al. taken from the Office Action including the Examiner's annotations.

Due to its location, however, at least a portion of the sample material could never move from the process chamber (602) into the mixing chamber (605) through the asserted mixing port (as recited in claims 1, 10, and 30) because the asserted mixing port is located on the wrong side of the mixing chamber (605). More specifically, the mixing port is not located between the process chamber (602) and mixing chamber (605) and, thus, sample material moving into the mixing chamber (605) from the process chamber (602) cannot move through the asserted mixing port.

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Regarding claims 6 and 7, nothing is identified within the disclosure of Kellogg et al. that teaches that the process chamber is located between a first major side and a second major side of the sample processing device, wherein at least a portion of the mixing chamber is located between the process chamber and the second major side of the sample processing device as recited in claim 6 or that substantially all of the mixing chamber is located between the process chamber and the second major side of the sample processing device as recited in claim 7. The result of such a construction is that at least a portion of the mixing chamber is located above or below the process chamber, thus offering the opportunity to save space on the device (see, e.g., Specification, p. 11, lines 11-14).

In support of the rejection of claims 6 and 7, it is asserted in the Office Action that the features of claims 6 and 7 are shown "when taking a cross section of the device." Office Action, May 20, 2008, pages 3-4. No cross-section is, however, identified within the disclosure of Kellogg et al. that depicts such features. Also, it appears that, from a cross-section of the device depicted in Figure 14 of Kellogg et al., the features recited in claims 6 and 7 are not found in the device depicted in Figure 14 of Kellogg et al. as would be required for a prima facie case of obviousness.

For at least these reasons, Applicants respectfully request reconsideration and withdrawal of the anticipation rejection of claims 1-3, 6-7, 9-10, 30-32, and 35 in view of Kellogg et al.

# The 35 U.S.C. § 103 Rejection

Claims 4-5, 8, and 33-34 were rejected under 35 U.S.C. § 103 as being unpatentable over Kellogg et al.

Applicants respectfully submit that, in view of the deficiencies of Kellogg et al. as discussed above with respect to the anticipation rejection, a *prima facie* case of obviousness has not been established with respect to claims 4, 5, 8, and 33-34. More specifically, no showing has been made as to how or why one of ordinary skill in the art would modify the teachings of Kellogg et al. to reach the claimed invention.

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For at least this reason, reconsideration and withdrawal of the obviousness rejection of claims 4-5, 8, and 33-34 are, therefore, respectfully requested.

## **Summary**

It is respectfully submitted that pending claims1-10 and 30-41 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

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22 SEPT. 2008

Date

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#### CERTIFICATE UNDER 37 CFR \$1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 22nd day of September, 2008, at 10.50 AW (Central Time).

y: San S-HV-ST Name: Sam E-Wiaant